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Arizona Administrative REGISTER

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From the Publisher

ABOUT THIS PUBLICATION

The authenticated pdf of the *Administrative Register* (A.A.R.) posted on the Arizona Secretary of State's website is the official published version for rulemaking activity in the state of Arizona.

Rulemaking is defined in Arizona Revised Statutes known as the Arizona Administrative Procedure Act (APA), A.R.S. Title 41, Chapter 6, Articles 1 through 10.

The *Register* is cited by volume and page number. Volumes are published by calendar year with issues published weekly. Page numbering continues in each weekly issue.

In addition, the *Register* contains notices of rules terminated by the agency and rules that have expired.

ABOUT RULES

Rules can be: made (all new text); amended (rules on file, changing text); repealed (removing text); or renumbered (moving rules to a different Section number). Rulemaking activity published in the *Register* includes: proposed, final, emergency, expedited, and exempt rules as defined in the APA, and other state statutes.

New rules in this publication (whether proposed or made) are denoted with underlining; repealed text is stricken.

WHERE IS A "CLEAN" COPY OF THE FINAL OR EXEMPT RULE PUBLISHED IN THE *REGISTER*?

The *Arizona Administrative Code* (A.A.C) contains the codified text of rules. The A.A.C. contains rules promulgated and filed by state agencies that have been approved by the Attorney General or the Governor's Regulatory Review Council. The *Code* also contains rules exempt from the rulemaking process.

The authenticated pdf of *Code* Chapters posted on the Arizona Secretary of State's website are the official published version of rules in the A.A.C. The *Code* is posted online for free.

LEGAL CITATIONS AND FILING NUMBERS

On the cover: Each agency is assigned a Chapter in the *Arizona Administrative Code* under a specific Title. Titles represent broad subject areas. The Title number is listed first; with the acronym A.A.C., which stands for the *Arizona Administrative Code*; following the Chapter number and Agency name, then program name. For example, the Secretary of State has rules on rulemaking in Title 1, Chapter 1 of the *Arizona Administrative Code*. The citation for this Chapter is 1 A.A.C. 1, Secretary of State, Rules and Rulemaking.very document filed in the office is assigned a file number. This number, enclosed in brackets, is located at the top right of the published documents in the *Register*. The original filed document is available for 10 cents a page.

Arizona Administrative REGISTER

July 1, 2022
Volume 28, Issue 26

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This publication is available online for free at www.azsos.gov.

ADMINISTRATIVE CODE
A price list for the *Arizona Administrative Code* is available online at www.azsos.gov.

PUBLICATION DEADLINES

Publication dates are published in the back of the *Register.* These dates include file submittal dates with a three-week turnaround from filing to published document.

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The Office of the Secretary of State is an equal opportunity employer.

Participate in the Process

Look for the Agency Notice

Review (inspect) notices published in the *Arizona Administrative Register.* Many agencies maintain stakeholder lists and would be glad to inform you when they proposed changes to rules. Check an agency's website and its newsletters for news about notices and meetings.

Feel like a change should be made to a rule and an agency has not proposed changes? You can petition an agency to make, amend, or repeal a rule. The agency must respond to the petition. (See A.R.S. § 41-1033)

Attend a public hearing/meeting

Attend a public meeting that is being conducted by the agency on a Notice of Proposed Rulemaking. Public meetings may be listed in the Preamble of a Notice of Proposed Rulemaking or they may be published separately in the *Register*. Be prepared to speak, attend the meeting, and make an oral comment.

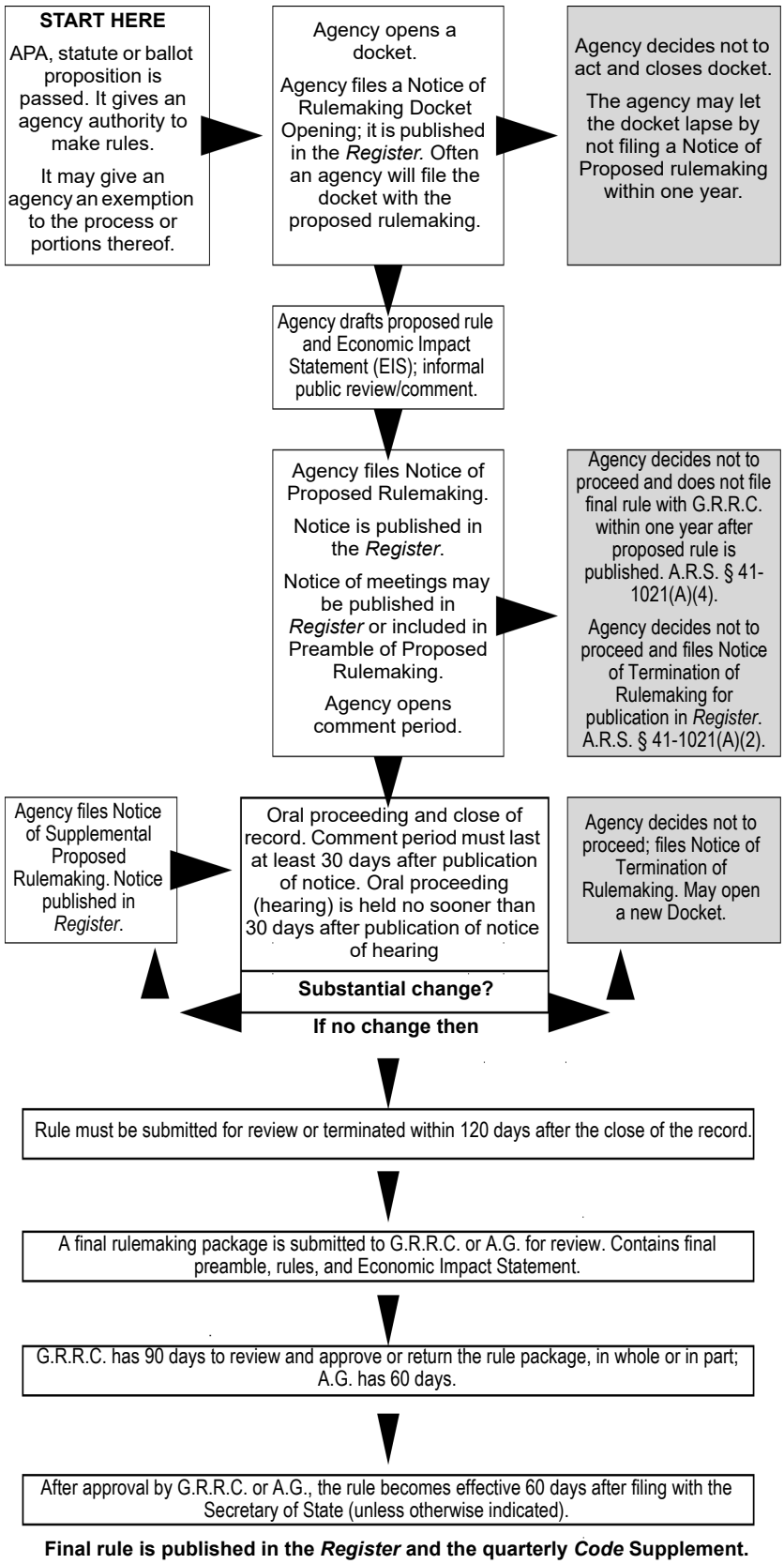
An agency may not have a public meeting scheduled on the Notice of Proposed Rulemaking. If not, you may request that the agency schedule a proceeding. This request must be put in writing within 30 days after the published Notice of Proposed Rulemaking.

Write the agency

Put your comments in writing to the agency. In order for the agency to consider your comments, the agency must receive them by the close of record. The comment must be received within the 30-day comment timeframe following the *Register* publication of the Notice of Proposed Rulemaking.

You can also submit to the Governor's Regulatory Review Council written comments that are relevant to the Council's power to review a given rule (A.R.S. § 41-1052). The Council reviews the rule at the end of the rulemaking process and before the rules are filed with the Secretary of State.

Arizona Regular Rulemaking Process



Definitions

***Arizona Administrative Code* (A.A.C.):** Official rules codified and published by the Secretary of State's Office. Available online at www.azsos.gov.

***Arizona Administrative Register* (A.A.R.):** The official publication that includes filed documents pertaining to Arizona rulemaking. Available online at www.azsos.gov.

Administrative Procedure Act (APA): A.R.S. Title 41, Chapter 6, Articles 1 through 10. Available online at www.azleg.gov.

Arizona Revised Statutes (A.R.S.): The statutes are made by the Arizona State Legislature during a legislative session. They are complied by Legislative Council, with the official publication codified by Thomson West. Citations to statutes include Titles which represent broad subject areas. The Title number is followed by the Section number. For example, A.R.S. § 41-1001 is the definitions Section of Title 41 of the Arizona Administrative Procedures Act. The "§" symbol simply means "section." Available online at www.azleg.gov.

Chapter: A division in the codification of the *Code* designating a state agency or, for a large agency, a major program.

Close of Record: The close of the public record for a proposed rulemaking is the date an agency chooses as the last date it will accept public comments, either written or oral.

Code of Federal Regulations (CFR): The *Code of Federal Regulations* is a codification of the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the federal government.

Docket: A public file for each rulemaking containing materials related to the proceedings of that rulemaking. The docket file is established and maintained by an agency from the time it begins to consider making a rule until the rulemaking is finished. The agency provides public notice of the docket by filing a Notice of Rulemaking Docket Opening with the Office for publication in the *Register*.

Economic, Small Business, and Consumer Impact Statement (EIS): The EIS identifies the impact of the rule on private and public employment, on small businesses, and on consumers. It includes an analysis of the probable costs and benefits of the rule. An agency includes a brief summary of the EIS in its preamble. The EIS is not published in the *Register* but is available from the agency promulgating the rule. The EIS is also filed with the rulemaking package.

Governor's Regulatory Review (G.R.R.C.): Reviews and approves rules to ensure that they are necessary and to avoid unnecessary duplication and adverse impact on the public. G.R.R.C. also assesses whether the rules are clear, concise, understandable, legal, consistent with legislative intent, and whether the benefits of a rule outweigh the cost.

Incorporated by Reference: An agency may incorporate by reference standards or other publications. These standards are available from the state agency with references on where to order the standard or review it online.

Federal Register (FR): The *Federal Register* is a legal newspaper published every business day by the National Archives and Records Administration (NARA). It contains federal agency regulations; proposed rules and notices; and executive orders, proclamations, and other presidential documents.

Session Laws or "Laws": When an agency references a law that has not yet been codified into the Arizona Revised Statutes, use the word "Laws" is followed by the year the law was passed by the Legislature, followed by the Chapter number using the abbreviation "Ch.", and the specific Section number using the Section symbol (§). For example, Laws 1995, Ch. 6, § 2. Session laws are available at www.azleg.gov.

United States Code (U.S.C.): The Code is a consolidation and codification by subject matter of the general and permanent laws of the United States. The Code does not include regulations issued by executive branch agencies, decisions of the federal courts, treaties, or laws enacted by state or local governments.

Acronyms

A.A.C. – *Arizona Administrative Code*

A.A.R. – *Arizona Administrative Register*

APA – Administrative Procedure Act

A.R.S. – Arizona Revised Statutes

CFR – *Code of Federal Regulations*

EIS – Economic, Small Business, and Consumer Impact Statement

FR – *Federal Register*

G.R.R.C. – Governor's Regulatory Review Council

U.S.C. – *United States Code*

About Preambles

The Preamble is the part of a rulemaking package that contains information about the rulemaking and provides agency justification and regulatory intent.

It includes reference to the specific statutes authorizing the agency to make the rule, an explanation of the rule, reasons for proposing the rule, and the preliminary Economic Impact Statement.

The information in the Preamble differs between rulemaking notices used and the stage of the rulemaking.

NOTICES OF FINAL RULEMAKING

This section of the *Arizona Administrative Register* contains Notices of Final Rulemaking. Final rules have been through the regular rulemaking process as defined in the Administrative Procedures Act. These rules were either approved by the Governor's Regulatory Review Council or the Attorney General's Office. Certificates of Approval are on file with the Office.

The final published notice includes a preamble and text of the rules as filed by the agency.

Economic Impact Statements are not published but are filed by the agency with their final notice.

The Office of the Secretary of State is the filing office and publisher of these rules. Questions about the interpretation of the final rules should be addressed to the agency that promulgated them. Refer to item #5 to contact the person charged with the rulemaking.

The codified version of these rules will be published in the *Arizona Administrative Code*.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 9. ~~EXPIRED~~DEPARTMENT OF HEALTH SERVICES PROCUREMENT ORGANIZATIONS

[R22-137]

PREAMBLE

1. Article, Part, or Section Affected (as applicable)	Rulemaking Action
Article 1	New Section
R9-9-101	New Section
R9-9-102	New Section
R9-9-103	New Section
R9-9-104	New Section
R9-9-105	New Section
R9-9-106	New Section
R9-9-107	New Section
R9-9-108	New Section
Table 1.1	New Section
Article 2	New Section
R9-9-201	New Section
R9-9-202	New Section
R9-9-203	New Section
R9-9-204	New Section
R9-9-205	New Section
Article 3	New Section
R9-9-301	New Section
R9-9-302	New Section
R9-9-303	New Section
R9-9-304	New Section
R9-9-305	New Section
Article 4	New Section
R9-9-401	New Section
R9-9-402	New Section
R9-9-403	New Section

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. §§ 36-132(A) and 36-136(G)

Implementing statute: A.R.S. §§ 36-851.01, 36-851.02, and 36-851.03

3. The effective date of the rules:

June 8, 2022

a. If the agency selected a date earlier than the 60 day effective date as specified in A.R.S. § 41-1032(A), include the earlier date and state the reason or reasons the agency selected the earlier effective date as provided in A.R.S. § 41-1032(A)(1) through (5):

The Arizona Department of Health Services (Department) requests an immediate effective date for the new rules under A.R.S. § 41-1032 (A)(4). The new rules in Chapter 9 prescribe measures necessary to provide standards for persons operating a procurement organization and provides donor services to ensure the health and safety of all individuals responsible

when caring for a donor. Additionally, the rules assist individuals responsible for a donor's wishes by providing requirements that are enforceable should a procurement organization be found to have violated a donor's wishes. The rules are the least burdensome, benefits applicants and individuals responsible for a donor, and protects the public while not affecting public involvement or public participation.

b. If the agency selected a date later than the 60 day effective date as specified in A.R.S. § 41-1032(A), include the later date and state the reason or reasons the agency selected the later effective date as provided in A.R.S. § 41-1032(B):

Not applicable

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Proposed Rulemaking: 28 A.A.R. 297, February 4, 2022
Notice of Rulemaking Docket Opening: 27 A.A.R. 851, June 4, 2021
Notice of Rulemaking Docket Opening: 26 A.A.R. 3098, December 4, 2020
Notice of Rulemaking Docket Opening: 25 A.A.R. 3319, November 15, 2019
Notice of Rulemaking Docket Opening: 24 A.A.R. 3108, November 2, 2018

5. The agency's contact person who can answer questions about the rulemaking:

Name: Thomas Salow, Interim Assistant Director
Address: Arizona Department of Health Services
Public Health Licensing Services
150 N. 18th Ave., Suite 400
Phoenix, AZ 85007-3232
Telephone: (602) 364-1935
Fax: (602) 364-4808
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or

Name: Robert Lane
Address: Arizona Department of Health Services
Office of Administrative Counsel and Rules
150 N. 18th Ave., Suite 200
Phoenix, AZ 85007
Telephone: (602) 542-1020
Fax: (602) 364-1150
Email: Robert.Lane@azdhs.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Laws 2016, Ch. 292 § 3, added A.R.S. §§ 36-851.01, 36-851.02, and 36-851.03. A.R.S. § 36-851.01 requires that a person acting as a procurement organization in Arizona be licensed by the Department, except as provided in A.R.S. § 36-851.01(F). A.R.S. § 36-851.02 specifies requirements for accredited procurement organizations, and A.R.S. § 36-851.03 specifies requirements for procurement organizations that are not accredited. Laws 2016, Ch. 292, § 4, requires the Department to "adopt rules relating to the licensure of procurement organizations and enforcement of those provisions." Additionally, Laws 2017, Ch. 171 in A.R.S. § 36-841 added a definition for "non-transplant anatomical donation organization" (NADO). Laws 2016, Ch. 292 added requirements specific to a NADO's scope of practice including donor acceptability and acquisition, traceability, transport, preparation, packaging, labeling, storage, release, evaluation of intended use, distribution and final disposition of non-transplant anatomical donation. Laws 2016, Ch. 292 also requires the Department to "adopt rules relating to the licensure of procurement organizations and enforcement of those provisions" and adopts rules that follow, as nearly as practicable, requirements equivalent to the accreditation requirements of a nationally recognized accrediting agency approved by the Department specified in A.R.S. § 36-851.03. The Department approves the American Association for Tissue Banks (AATB) Standards for Non-Transplant Anatomical Donations, 2nd Edition. The rulemaking adds new: Arizona Administrative Code Title 9, Ch. 9; Article 1, Procurement Organization Licensure; Article 2, Administration for a Non-Accredited Procurement Organization; Article 3, Physical Plant; Transportation for a Non-Accredited Procurement Organization; and Article 4, Administration for an Accredited Procurement Organization. The Department plans to promulgate rules in Title 9, Ch. 9 through regular rulemaking according to A.R.S. Title 41**,** Chapter 6. The rulemaking conforms to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

7. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A summary of the economic, small business, and consumer impact:

In the 2022 Economic, Small Business, and Consumer Impact Statement, annual cost/revenue associated with this rulemaking are

designated as minimal when more than $0 and less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000. Costs and benefits are indicated as significant when meaningful or important and not readily subject to quantification. No new FTEs are required due to this rulemaking. The Department identifies affected persons as the Department, non-transplant procurement organizations, organ procurement organizations, providers of retail services, education and research facilities, and donors, a donor's family, and individuals responsible for a donor. The Department anticipates it will incur a moderate cost related to promulgating rules and establishing a program to license non-transplant procurement organizations, including the administration, application process, and inspections. The Department also anticipates that a moderate benefit may occur for having rules allowing the Department to inspect non-transplant procurement organizations rather than responding to a concerned citizen reporting a public nuisance. Non-transplant procurement organizations may incur a moderate benefit for having an Arizona state license posted that allows individuals seeking services to confirm that a non-transplant procurement organization is licensed by the state and is compliant with state laws. Non-transplant procurement organizations may incur a moderate cost related to the licensing fee. However, an accredited non-transplant procurement organizations who chooses to drop accreditation for Arizona state license may receive a significant benefit from reduced costs for no longer having to comply with AATB's required fees for accreditation. Since accredited non-transplant procurement organization already operate according to the AATB Standards for Non-Transplant Anatomical Donations and the accredited non-transplant procurement organizations are mostly compliant with the proposed procurement organization rules, the Department expects an accredited non-transplant procurement organization's cost to be limited to the fee paid to obtain an Arizona license.

Providers of retail services who provide medical supplies and devices, reagents, testing materials, transport services, and other related devices, materials, and services are not expected to incur additional costs or benefits from accredited non-transplant procurement organizations. However, if a new non-transplant procurement organization were to open, providers of retail services may receive a substantial benefit for selling goods and services to a newly established licensed non-transplant procurement organization. Similarly, education and research facilities may receive a substantial benefit for having another source from whom non-transplant anatomical material may be procured. Lastly, the Department expects a donor, a donor's family, and individuals responsible for a donor may receive a substantial benefit for having a state licensed non-transplant procurement organization accepting their donation that will respect and use the donation as agreed to in the donor consent form. The Department does not expect donors, donor's family, and individuals responsible for a donor will incur any costs, since the non-transplant procurement organizations cover costs associated with a donor or donation, including transfer of the donor, filing death certificate, and performing final disposition (cremation). The Department has determined that the benefits received for having rules that license non-transplant procurement organization outweigh the potential costs associated with this rulemaking.

10. A description of any changes between the proposed rulemaking, including supplemental notices, and the final rulemaking:

The Department received nine comments between the proposed rulemaking and the final rulemaking. Two comments addressed the same matter and the Department agreed with the commenters and deleted a requirement in R9-9-204(F)(3)(c) for licensed procurement organizations to maintain "Evidence of freedom from infections tuberculosis, if applicable." An additional comment was received related to International Air Transport Association and Transport Security Administration. The Department changed R9-9-304(B) to clarify use of vehicle and air transportations. The Department has identified each commenter and the Department's responses to each comment received in item 11.

11. Agency's summary of the public or stakeholder comments or objections made about the rulemaking and the agency response to the comments:

During the formal 30-day public comment period, the Department received three written comments from the Isaacson Law Firm, on behalf Science Care, Inc. Science Care, Inc. and six written survey comments from Willetta Partners, on behalf of Research for Life. Both are AATB accredited non-transplant procurement organization operating in Arizona.

(A.) R9-9-106.A.2. Respectfully request that OHS [DHS] reconsider modifying R9-9-106.A.2. by inserting "that alters the designated area for tissue recovery" after the word modification. Although Science Care recognizes that OHS [DHS] licenses the entire facility, as mentioned previously, an alteration of an office or conference room is not a change that should affect a license. A concern is that such a modification may be made without the licensee contemplating that this could possibly impact a procurement organization's license and fail to notify the OHS [DHS]. Currently the rule states: "A proposed modification, if applicable." A licensee would probably not consideran alteration of an office or conference room as applicable to the license.

Department Response: The Department does not agree with Science Care interpretation; and the rule does not require a licensee to notify the Department of all modifications (defined in rule and definition below) made to a licensed facility. The term "modification" is defined in rule and specifies "substantial improvement." Additionally, A.R.S. § 36-841(16) specifies the services and activities a procurement organization facilitates. The Department expects a substantial improvement made at a licensed facility affecting the operations, services, and activities defined in A.R.S. § 36-841(16) requires notification be made to the Department. If a licensee operating an accredited procurement organization modifies office space that has nothing to do with the licensed facility's operation or licensed services and activities related to A.R.S. § 36-851.02, the licensee is not required to notice the Department. Note: Recall, R9-9-106 applies to non-accredited and accredited procurement organizations. In R9-9-106 (A)(2), "if applicable" is used so an accredited procurement organization licensed in Arizona – determines whether to notify or not notify the Department. Refer to: R9-9-101(22) "Modification" means the substantial improvement, enlargement, reduction, alternation, or other substantial change in the facility or another structure on the premises at a procurement organization.

The rule is consistent with AATB STANDARDS: NT-K1.200 (13) - The design or the arrangement of the physical plant to meet operational needs such as designation of spaces, *environmental monitoring*, and security (*series of standards* at NT-K4.000). **NT-K4.100** GENERAL - The physical plant *shall* be designed or arranged to meet operational needs. The prem-

ises *shall* be maintained in a clean, and orderly manner with adequate plumbing, drainage, lighting, ventilation and space. Adequate, clean, and convenient hand-washing and eye-washing facilities *shall* be available for personnel.

(B.) R9-9-204.F.3.c. Respectfully request that OHS [DHS] reconsider requiring a non-accredited procurement organization to document individuals are free from infectious tuberculosis, if applicable. This is not something procurement organizations currently ask their employees and do not believe it is applicable to procurement organizations.

Department Response: The Department revisited AATB Standards related to stakeholder request, and after reconsideration, the Department amended R9-9-204(F)(3) and deleted subsection (c) that requested documentation applicable to an individual's duties.

Deleted: (F)(3)(c) "Evidence of freedom from infectious tuberculosis, if applicable."

The Department based its decision on consideration of subsection NT-K3.400 that provides "Universal Precautions, as defined by CDC[1], shall be implemented and enforce to reduce the potential exposure of staff to communicable disease." Additionally, the CDC, National Institute for Occupational Safety and Health, published an overview stating "Exposures to blood and other body fluids occur across a wide variety of occupations. Health care workers, emergency response and public safety personnel, and other workers can be exposed to blood through needlestick and other sharps injuries, mucous membrane, and skin exposures. The pathogens of primary concern are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Workers and employers should take advantage of available engineering controls and work practices to prevent exposure to blood and other body fluids.

(C.) R9-9-303. Respectfully request that DHS add the additional security options outlined in the AATB standards found in NT-K4-300 by adding configuration of the physical plant. Again, ARS 36-851.03.C. states the DHS shall adopt rules that follow, as nearly as practicable, the requirements as set forth in the accreditation requirements of a nationally recognized accrediting agency that is approved by the department.

Department Response: The Department communicated with commenter, and after discussion, commenter agreed that the rule is mostly consistent with NT-K4-300. The commenter recognized that defining "configuration of the physical plant" is difficult-subjective. Commenter retracted request to add "configuration of the physical plant."

NT-K4.300 SECURITY … *NADOs shall* maintain adequate

[1] physical security to safeguard *NAM* inventory and *records* as well as to Ref. R9-9-303(B)(1)

[2] prevent the entry of unauthorized individuals. Such security *may* be Ref. R9-9-303(B)

[3] in the form of personnel, electronic or mechanical devices, or **configuration of the physical plant**.

Ref. R9-9-303(B) includes personnel/mechanical/electronic

[4] Limited access areas *shall* be *established* as appropriate, Ref. R9-9-303(B)(5)

[5] permitting entry of only those personnel (including auditors and inspectors) who are authorized by supervisory personnel. Ref. R9-9-303(B)(5)

(D.) R9-9-101.42 Requested Modification: "Transport" means a method for relocating NAM from one place to another OUTSIDE OF THE FACILITY in a manner that provides conditions necessary to maintain the quality of the NAM for its intended use." **Reasoning:** Quality is not defined. Also, it is not reasonable to require a definition of how NAM is moved inside the facility.

Department Response:

(1) The Department does not define the word "quality" used in the definition since the word does not stand alone, and the Department expects that the dictionary definite is acceptable. As used in the definition "condition necessary to maintain the quality of the NAM for its intended use", the NAM is expected to endure transport in a matter that will not cause the NAM to deteriorate in such a way that would cause the NAM to arrive in state that would prevent the NAM from being used as intended by an educational or research facility requesting the NAM. The Webster dictionary defines "quality" to mean a degree of excellence, essential character, and grade.

(2) The Department agrees with commenter that "how NAM is moved inside the facility" is not necessary. The Department clarifies that the word "transport" is not used in the rules for "how NAM is moved inside the facility". The word "transport" is used in R9-9-304, Transportation Standards, and in R9-9-305, Sanitation Standards and Reporting. In R9-9-304(A), the requirement states, "If a non-accredited procurement organization owns and maintains a vehicle for transporting NAM, an administrator shall ensure the vehicle is: …" and ib subsection (B) states "If using another vehicle for transporting NTAD or NAM, an administrator … shall ensure the other vehicle…" In R9-9-305(A)(3), a requirement requires a "licensee…shall ensure that all transport vehicles, …"

Note: The word "transport", as used in the rules, means a method [a vehicle] for relocating NAM from one place to another in a manner that provides conditions [a premise upon which the fulfillment of an agreement depends] necessary to maintain [to keep in an existing state] the quality [essential character] of the NAM for its intended [expected to be such in the future] use.

(E.) R9-9-104.A.1.h Requested Modification: "Whether the applicant complies with local zoning ordinances, building codes, and fire codes;" **Reasoning:** Building codes and fire codes are a local issue. While they change over time, current uses are grandfathered. This provision would create confusion.

Department Response: The Department is aware and agrees with the commenter that jurisdictions regulating local zoning ordinances, building codes, and fire codes allow for variances for various reasons. During an inspection, should the Depart-

1. Bloodborne Infectious Diseases: HIV/AIDS, Hepatitis B, Hepatitis C

ment request information specified in rules to verifying complies with zoning ordinances, building codes, and fire codes, the accredited non-transplant procurement organization should provide the information requested including any variance provided by a local jurisdiction. There is no confusion in providing the Department with a document that explains the matter being inspected. The Department experiences this type of incident on occasion since this requirement is included in other Department rules for licensing facilities.

(F.) R9-9-204.F.3.c Requested Modification: "Evidence of freedom from infectious tuberculosis, if applicable; and" **Reasoning:** This is not applicable to procurement organizations.

Department Response: The Department received a similar comment from Science Care, above, refer to subsection (B.). The Department states it will delete the requirement to provide "Evidence of freedom from infectious tuberculosis, if applicable."

(G.) R9-9-301.A.1c Requested Modification: "Has equipment and supplies to maintain NTAD and NAM PER STANDARD OPERATING PROCEDURES in a safe and temperature-controlled state; and" **Reasoning:** What does safe mean? It is not defined.

Department Response: The requirement in the Notice of Proposed Rulemaking states, "Has equipment and supplies to maintain NTAD and NAM in a safe and temperature-controlled;". The Department does not define the word "safe" in the rules and rather uses the Webster dictionary to mean "free from harm or risk." The word "safe" is also in R9-13-403, Tissue End-User, (A)(1)(d) stating "A description of the venue in which the NAM will be used and the security measures for the safe and ethical utilization of the venue:" Additionally, this requirement is cited in the AATB Standards, NT-G1.100(5) and unfortunately, the AATB Standard does not define the word "safe." The Department expects the use of the word "safe" in this requirement is consistent with the other requirements in rule and AATB Standards.

(H.) R9-9-301.A.3.b Requested Modification: "Does not contain any items, materials, or devices associated with the preparation activities or technicians and personnel members;" **Reasoning:** This issue is taken care of by item 'a' above.

Department Response: The Department accepts statement "This issue is taken care of by item 'a' above." to mean a response by the Department is not required.

(I.) R9-9-304.B.3 Requested Modification: "If transport is by air, complies CONTRACTURALLY REQUIRE TRANSPORTATION VENDER TO COMPLY with applicable standards established by the International Air Transport Association and Transport Security Administration." **Reasoning:** A procurement organization has no control over or ability to manage compliance with IATA and TSA requirements. All that can be done is require compliance with IATA and TSA requirements in the contracts with transportation vendors.

Department Response: The Department reviewed the request to add "contractually require transportation vendor to comply" in R9-9-304(B)(3). The Department also understands that a licensed non-accredited procurement organization has no control over or ability to manage an air transportation vendor's compliance with IATA and TSA guidelines. To clarify, the intent of the rule is for a licensed non-accredited procurement organization in an agreement with an air transportation vendor to include a statement that the air transportation vendor acknowledges services provided are consistent with IATA and TSA guidelines when transporting NTAD or NAM. The Department understands that an air transportation vendor may not comply with IATA or TSA guidelines whether due to an accident, error, or willful neglect. The Department changes the requirement, as shown below, to make clearer the intent of the requirement in R9-9-304(B)(3). The Department expects procurement organizations will also clarify the rule's intent in its SOP governing NTAD and NAM transportation.

B. If ~~uses~~ using another vehicle or type of transport for ~~transporting~~ NTAD or NAM, an administrator of a non-accredited procurement organization shall ensure that another vehicle or type of transport:
   1. Is properly equipped for the transportation of NTAD or NAM;
   2. Is compliant with all state laws and rule pertaining to transporting humans remains; and
   3. If transport is by air, complies with ~~the air transportation vendor provides statement that air transportation services for NTAD or NAM are~~ applicable standards established by the International Air Transport Association and Transport Security Administration.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

There are no other matters prescribed by statute applicable specifically to the Department or this specific rulemaking.

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

In R9-9-102, the rule specifies that a person may not act as a procurement organization in Arizona unless the person is licensed by the Department as a procurement organization and a general permit is not used. The Department cites A.R.S. § 36-851.01 that requires the Department to grant a procurement organization license to a person if the procurement organization is accredited by a nationally recognized accrediting agency approved by the Department or meets the requirements prescribed in rules adopted by the Department. Additionally, the Department cites A.R.S. § 41-1037(A)(2)[2] that exempts the Department from a requirement to issue a general permit specified in A.R.S. § 41-1037(A).

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

No federal law is applicable to the subject of the rule.

[2] The issuance of an alternative type of permit, license or authorization is specifically authorized by state statute.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:
No analysis comparing competitiveness was received by the Department.

13. Incorporated by reference and their location in the rules:
Not applicable

14. Whether the rule was previously made, amended, or repealed as an emergency rules. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:
The rule was not previously made as an emergency rule.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 9. ~~EXPIRED~~DEPARTMENT OF HEALTH SERVICES PROCUREMENT ORGANIZATIONS

ARTICLE 1. PROCUREMENT ORGANIZATION LICENSURE

Section

ARTICLE 2. ADMINISTRATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

Section

ARTICLE 3. PHYSICAL PLANT; TRANSPORTATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

Section

ARTICLE 4. ADMINISTRATION FOR AN ACCREDITED PROCUREMENT ORGANIZATION

Section

ARTICLE 1. PROCUREMENT ORGANIZATION LICENSURE

R9-9-101. Definitions
In addition to the definitions in A.R.S. § 36-841, the following apply in this Chapter unless otherwise specified:

1. "Acceptability assessment" means the evaluation of available, if applicable, medical information about a donor to determine whether the donor meets qualifications as established by SOPs specified in R9-9-201(E)(4).
2. "Accrediting body" means a nationally recognized agency, approved by the Department, that provides certification for a person operating a procurement organization.
3. "Acquisition" means activities required to obtain a NTAD that is intended for use in education or research.
4. "Administrative completeness review time-frame" has the same meaning as in A.R.S. § 41-1072.
5. "Administrator" means the individual responsible for the services and activities provided by a procurement organization.
6. "Applicant" means an individual or business organization requesting approval to operate a procurement organization.
7. "Application packet" means the information, documents, and fees required by the Department for licensure of a procurement organization.
8. "Authorization" means permission given for NTAD acquisition by a donor or individual authorized by law.

9. "Business organization" means the same as "entity" in A.R.S. § 10-140.
10. "Calendar day" means each day, not including the day of the act, event, or default from which a designated period of time begins to run, but including the last day of the period unless it is a Saturday, Sunday, statewide furlough day, or legal holiday, in which case the period runs until the end of the next day that is not a Saturday, Sunday, statewide furlough day, or legal holiday.
11. "Controlling person" means an individual who, with respect to a business organization:
    a. Has the power to vote at least 10% of the outstanding voting securities of the business organization;
    b. If the business organization is a partnership, is a general partner or is a limited partner who holds at least 10% of the voting rights of the partnership;
    c. If the business organization is a corporation, association, or limited liability company, is the president, the chief executive officer, the incorporator, an agent, or any individual who owns or controls at least 10% of the voting securities; or
    d. Holds a beneficial interest in 10% or more of the liabilities of the business organization.
12. "Contracted services" means functions pertaining to the acquisition, screening, testing, preparing, storage, and distribution of NAM that another establishment agrees to perform.
13. "Department" means the Arizona Department of Health Services.
14. "Distribution" means a process that includes selection and evaluation of intended use of NAM for release to another procurement organization, an education facility, or a research facility.
15. "Donor consent form" means the same as "document of gift" defined A.R.S. § 36-841.
16. "Environmental services" means activities such as housekeeping, laundry, facility maintenance, or equipment maintenance.
17. "Exceptional release" means NAM that is approved for usage before a donor acceptability assessment or by a researcher requesting NAM that would not normally meet the established acceptability criteria.
18. "Final disposition" means the disposal of NAM through incineration, cremation, bio-cremation, burial, fully depleted by virtue of a particular use, or by another legal means.
19. "Licensee" means a person to whom the Department has issued a license to operate a non-transplant procurement organization or person designated by the licensee.
20. "Medical director" means a physician licensed in this state pursuant to A.R.S. Title 32, Chapter 13 or 17 who provides medical guidance for a licensed procurement organization according to A.R.S. § 36-851.03 or person designated by the medical director.
21. "Misuse" means to use NTAD and NAM for purposes other than for:
    a. Education or research, and
    b. Uses specified on a donor consent form.
22. "Modification" means the substantial improvement, enlargement, reduction, alternation, or other substantial change in the facility or another structure on the premises at a procurement organization.
23. "Non-transplant anatomical donation" or "NTAD" means a donation of a whole body, organs or tissues authorized and used for education and research prior to release to distribution inventory.
24. "Non-transplant anatomical material" or "NAM" means a whole body or parts of a body donated for use in education or research that has been prepared, packaged, labeled, and released to distribution inventory.
25. "Overall time-frame" means the same as in A.R.S. § 41-1072.
26. "Person" means the same as in A.R.S. § 36-841.
27. "Personnel member" means individuals identified as employees, students, or volunteer who provides services and activities for a procurement organization.
28. "Pest control" means activities that minimize the presence of insects and vermin in a procurement organization to ensure the quality of NTAD and NAM and the health and safety of persons occupying or visiting.
29. "Physical assessment" means a postmortem documented evaluation of a deceased donor's body that may identify evidence of: high-risk behaviors, signs of HIV infection or hepatitis infection, other viral or bacterial infections, and trauma.
30. "Premises" mean a facility and surrounding grounds that are:
    a. Designated by an applicant or a licensee;
    b. Used for providing procurement organization services and activities; and
    c. Licensed by the Department as a procurement organization.
31. "Preparation" means any activity performed other than donor screening, donor testing, acquisition, storage, distribution, or dispensing functions to enable the use of NAM for education or research. It includes, but is not limited to, cleaning, preservation, disarticulation, dissection, skeletonization, plastination, packaging, and labeling of NAM.
32. "Procurement organization" means the same as "non-transplant anatomical donation organization" as defined in A.R.S. § 36-841 and may be either accredited by an accrediting body or non-accredited.
33. "Quality management program" means ongoing activities designed and implemented by a procurement organization to improve the delivery of services and activities related to NAM.
34. "Quarantine" means the identification of NTAD or NAM as not acceptable or yet to be determined as eligible for use in education or research, including NTAD or NAM whose suitability has not been determined.
35. "Release" means NAM approved by a procurement organization in accordance with criteria established by the medical director for transfer to an approved education and research facility.
36. "Risk assessment" means collecting and evaluating relevant medical history and social behavior obtained from an individual or individuals who have knowledge about the donor.
37. "Standard operating policies and procedures" or "SOPs" means a group of documents detailing the specific purposes and services provided by a licensed procurement organization including activities and methods by staff and personnel members in support of conducting business operations.
38. "Storage" means a designated area that contains equipment, instruments, and supplies to maintain NTAD or NAM until distribution or final disposition.
39. "Substantive review time-frame" means the same as in A.R.S. § 41-1072.

40. "Traceability" means the method to locate NTAD and NAM during any step of NTAD including obtaining authorization, acquisition, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluation intended use, distribution, and final disposition.
41. "Transfer" means the conveyance or relocation of NAM to:
    a. An education facility,
    b. A research facility,
    c. Another procurement organization, or
    d. A distribution inventory.
42. "Transport" means a method for relocating NAM from one place to another in a manner that provides conditions necessary to maintain the quality of the NAM for its intended use.
43. "Universal precautions" means the same as in A.R.S. § 32-1301.
44. "Working day" means a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state and federal holiday or a statewide furlough day.

R9-9-102. Licensure Requirements; Accreditation; Exemptions

A. A person may not act as a procurement organization in this state unless the person is licensed by the Department as a procurement organization.

B. A procurement organization shall provide a designated area for tissue recovery that does not operate in a funeral establishment specified in A.R.S. § 32-1301, for the recovery of whole bodies for medical research and education according to A.R.S. §§ 36-851.02(3) and 36-851.03(A)(5)(b).

C. A non-accredited procurement organization is subject to inspection by the Department at any time to evaluate compliance with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter according to A.R.S. § 36-851.03(A)(5)(a) and (C).

D. An accredited procurement organization is subject to inspection by the Department at any time to evaluate compliance with requirements in A.R.S. § 36-851.02(2) and the rules adopted pursuant to A.R.S. § 36-851.02(2).

E. An accredited procurement organization whose certificate of accreditation has expired or is revoked, suspended, or denied by the accrediting body, shall provide written notification to the Department within ten working days of expiration or receipt of a revocation, suspension, or denial.

F. This Chapter does not apply to a procurement organization identified in A.R.S. § 36-851.01(F).

R9-9-103. Individuals to Act for an Applicant or Licensee

When an applicant or licensee is required by this Chapter to provide information on or sign an application form or other document, the following shall satisfy the requirement on behalf of the applicant or licensee:

1. If the applicant or licensee is an individual, the individual; and
2. If the applicant or licensee is a business organization, the individual who the business organization has designated to act on the business organization's behalf for purposes of this Chapter and who:
    a. Is a controlling person of the business organization,
    b. Is a U.S. citizen or legal resident, and
    c. Has an Arizona address.

R9-9-104. Application for Licensure

A. An applicant applying for a procurement organization license shall submit an application packet that contains:
1. An application, in a Department-provided format, according to A.R.S. § 36-851.01(A) that includes:
    a. The applicant's name, mailing address, email address, and telephone number;
    b. The name or proposed name of the procurement organization, including the:
        i. Business street address;
        ii. Business mailing address, if different from the street address;
        iii. Telephone number;
        iv. Email address; and
        v. Tax ID number;
    c. If part of a business institution, the institution's:
        i. Name;
        ii. Street address;
        iii. Mailing address, if different from the street address;
        iv. Telephone number; and
        v. Email address;
    d. Whether the procurement organization is ready for a licensing inspection by the Department, if applicable;
    e. If the procurement organization is not ready for a licensing inspection specified in (d), the date the Department may perform a licensing inspection, if applicable;
    f. The name and contact information of an individual acting on behalf of the applicant specified in R9-9-103, if applicable;
    g. If applicable, the medical director's:
        i. Name,
        ii Telephone number,
        iii. Email address, and
        iv. License number;
    h. Whether the applicant complies with local zoning ordinances, building codes, and fire codes;
    i. Whether the applicant agrees to allow the department to submit supplemental requests for information under R9-9-108; and
    j. The applicant's signature and the date signed;

2. A copy of the procurement organization's current certificate of accreditation from an accrediting body, if applicable;
3. Documentation for the applicant that complies with A.R.S. § 41-1080;
4. A copy of the procurement organization labeled floor plan, including technical and administrative function areas, if applicable; and
5. A licensing fee of $2,000.

B. Upon receipt of the application packet in subsection (A), the Department shall conduct an inspection of the procurement organization, if applicable.

C. The Department shall issue or deny a license to an applicant as specified in R9-9-108.

R9-9-105. Application for License Renewal

A. A license is valid for two years from the date of issuance or renewal as specified in A.R.S. § 36-851.01(C).

B. At least 30 calendar days before the expiration date indicated on a procurement organization's license to operate a licensee shall submit to the Department an application packet for renewal of the license that contains:
1. An application, in a Department-provided format, that includes:
   a. The applicant's name, mailing address, email address, and telephone number;
   b. The procurement organization's licensing number; and
   c. Whether the applicant agrees to allow the Department to submit supplemental requests for information under R9-9-108;
2. If applicable, documentation of the most recent certificate of accreditation from an accrediting body; and
3. A licensing renewal fee of $2,000.

C. The Department shall renew or deny renewal of a license to operate as specified in R9-9-108.

R9-9-106. Changes Affecting a License

A. A licensee shall notify the Department in writing at least 30 calendar days before the effective date of:
1. Termination of operation, including:
   a. The proposed termination date; and
   b. The address and contact information for the location where the procurement organization records will be retained as required in R9-9-205;
2. A proposed modification, if applicable;
3. A change in the legal name of a procurement organization;
4. A change in the legal name of a licensee including the licensee's new name; and
5. A change in the address of a procurement organization, including the new address.

B. A licensee shall notify the Department in writing at least 30 calendar days after the effective date of a change in:
1. The email address or mailing address of a procurement organization including the new email address or mailing address;
2. The email address or telephone number of a licensee, including the new email address or telephone number;
3. An administrator, including the name, telephone number, and email address;
4. A medical director, including the name and email address; and
5. The name, telephone number, and email address of an individual acting on behalf of the licensee specified in R9-9-103.

C. If the Department receives the notification of termination of operation in subsection (A)(1), the Department shall void the licensee's license to operate a procurement organization as of the termination date specified by the licensee.

D. If the Department receives a notification in subsection (A)(2) of a proposed modification, the Department:
1. May conduct an inspection of the premises as allowed by A.R.S. § 36-851.03(C); and
2. Shall issue to the licensee an amended license that incorporates the modification and retains the expiration date of the existing license, if the procurement organization is compliant with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter.

E. If the Department receives a notification in subsection (A)(3) of a legal name change for a procurement organization, the Department shall issue to the licensee an amended license showing the licensee's legal name.

F. If the Department receives notice for a change in the legal name of a licensee in subsection (A)(4), the Department shall void licensee's license to operate upon issuance of a new license to operate.

G. If the Department receives the notice for a change in the address of a procurement organization in subsection (A)(5), the Department shall review the application for a new license, submitted consistent with R9-9-104.

H. An individual or business organization planning to take ownership of an existing procurement organization shall obtain a new license before beginning operation.

R9-9-107. Denial, Suspension, Revocation, Enforcement

A. The Department may:
1. Deny a license as specified in subsection (B);
2. Suspend or revoke a license under A.R.S. § 36-851.01(E) and subsection (B); or
3. Assess or impose a civil penalty under A.R.S. § 36-851.01(E) and subsection (B).

B. The Department may impose civil penalties, deny an application or suspend or revoke a license to operate a procurement organization, if:
1. An applicant or licensee does not meet the application requirements contained in R9-9-104 and R9-9-105, as applicable;
2. A licensee does not comply with requirements in A.R.S. §§ 36-851.01 through 36-851.03 and this Chapter, if applicable;
3. A licensee does not correct the deficiencies identified during an inspection according to the plan of correction;
4. An applicant or licensee provides false or misleading information to the Department; or
5. The nature or number of violations revealed by any type of inspection or investigation of a procurement organization poses a direct risk to the life, health, or safety of individuals on the premises.

C. In determining which action in subsection (A) is appropriate, the Department shall consider:
1. Repeated violations of statutes or rules,

2. Pattern of violations,
3. Severity of violations, and
4. Number of violations.

D. The Department may suspend or revoke an accredited procurement organization's license if the Department receives notice that the accredited procurement organization's accreditation has expired or has been suspended or revoked by the accrediting body.

E. An applicant or licensee may appeal the Department's determination in this Section according to A.R.S. Title 41, Chapter 6, Article 10.

R9-9-108. Time-frames

A. The overall time-frame for a license granted by the Department under this Chapter is set forth in Table 1.1. The applicant or licensee and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. An extension of the substantive review time-frame and the overall time-frame may not exceed 25% of the overall time-frame.

B. The administrative completeness review time-frame for a license granted by the Department under this Chapter is set forth in Table 1.1 and begins on the date that the Department receives an application packet:

1. The Department shall send a notice of administrative completeness or deficiencies to the applicant or licensee within the administrative completeness review time-frame:
   a. A notice of deficiencies shall list each deficiency and the information or items needed to complete the application;
   b. The administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice of deficiencies is sent until the date that the Department receives all of the missing information or items from the applicant or licensee;
   c. If an applicant or licensee fails to submit to the Department all of the information or items listed in the notice of deficiencies within 120 calendar days after the date that the Department sent the notice of deficiencies or within a time period the applicant or licensee and the Department agree upon in writing, the Department shall consider the application withdrawn; and
2. If the Department issues a license during the administrative completeness review time-frame, the Department shall not issue a separate written notice of administrative completeness.

C. The substantive review time-frame is set forth in Table 1.1 and begins on the date of the notice of administrative completeness:

1. As part of the substantive review of an application for a license, the Department may conduct an inspection according to A.R.S. § 36-851.03(C) that may require more than one visit to complete.
2. The Department shall send a license or a written notice of denial of a license within the substantive review time-frame.
3. During the substantive review time-frame, the Department may make one comprehensive written request for additional information, unless the applicant or licensee has agreed in writing to allow the Department to submit supplemental requests for information:
   a. The Department shall send a comprehensive written request for additional information that includes a written statement of deficiencies, stating each statute and rule upon which noncompliance is based, if the Department determines that an applicant or licensee, and the procurement organization, including the premises are not in substantial compliance with A.R.S. Title 36, Chapter 7, Article 3 or this Chapter;
   b. An applicant or licensee shall submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of the corrections required in a statement of deficiencies, within 30 calendar days after the date of the comprehensive written request for additional information or the supplemental request for information or within a time period the applicant or licensee and the Department agree upon in writing;
   c. The substantive review time-frame and the overall time-frame are suspended from the date that the Department sends a comprehensive written request for additional information or a supplemental request for information until the date that the Department receives all of the information requested, including, if applicable, documentation of corrections required in a statement of deficiencies; and
   d. If an applicant or licensee fails to submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of corrections required in a statement of deficiencies, within the time prescribed in subsection (C)(3)(b), the Department shall deny the application.
4. The Department shall issue a license if the Department determines that the applicant or licensee and the procurement organization, including the premises, are in substantial compliance with A.R.S. Title 36, Chapter 7, Article 3 and this Chapter.
5. If the Department denies a license, the Department shall send to the applicant or licensee a written notice of denial setting forth the reasons for denial and all other information required by A.R.S. §§ 41-1076 and 41-1092.03.

Table 1.1. Time-frames (in calendar days)

Type of Approval	Statutory Authority	Overall Time-Frame	Administrative Completeness Review Time-Frame	Substantive Review Time-Frame
Application for Licensure	A.R.S. § 36-851.01	90	30	60
Application for License Renewal	A.R.S. § 36-851.01	30	10	20
Modification Change Request Affecting License	A.R.S. § 36-851.01	60	30	30

ARTICLE 2. ADMINISTRATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

R9-9-201. Administration

A. A licensee for a non-accredited procurement organization:

1. Is responsible for all issues of liability, ethical considerations, fiduciary issues, and compliance with applicable laws and regulations;
   a. SOPs for all activities and services the procurement organization provides;
   b. The qualifications for an administrator:
      i. Who has at least a bachelor's degree in a health science or other science related field, and
      ii. Is responsible for all services and activities at a procurement organization; and
   c. The qualifications for a medical director:
      i. Who is licensed pursuant to A.R.S. Title 32, Chapter 13 or 17; and
      ii. Provides medical guidance to determine donor eligibility;
2. Shall adopt a quality management program; and
3. Shall review and evaluate the effectiveness of the quality management program in R9-9-202 at least once every 12 months.

B. An administrator of a non-accredited procurement organization:
1. Is directly accountable to the licensee for the operation, including all services and activities, provided by or at the procurement organization;
2. Has the authority and responsibility to manage the procurement organization as specified in SOPs;
3. Designates, in writing, an individual who is on the procurement organization's premises and is available when the administrator is not present on the premises.

C. A medical director of a non-accredited procurement organization:
1. Shall provide medical guidance to determine and establish donor eligibility as established in R9-9-204; and
2. May be the same individual as the administrator, if the individual's qualifications include management for all services and activities provided at a procurement organization.

D. A licensee of a non-accredited procurement organization shall ensure that the following programs at the procurement organization are established and maintained in compliance with state and federal laws and regulations:
1. A safety awareness and blood-borne pathogen training program; and
2. A cleaning program that mitigates potential cross-contamination between NTAD.

E. A licensee of a non-accredited procurement organization shall ensure that:
1. The procurement organization complies with vital records requirements in A.R.S. § 36-325;
2. An identification system according to A.R.S. § 36-851.03(A)(3)(b) for donors:
   a. Is established and maintained, and
   b. Assigns a unique identification number according to A.R.S. § 36-851.03(A)(6)(a);
      i. For each donor, and
      ii. Used to identify all NAM from a donor that is recovered and distributed;
3. SOPs are established, documented, and implemented that includes:
   a. Job descriptions, duties, and qualifications, including required skills, knowledge, education, and experience for technicians and personnel members;
   b. Orientation and in-service education for technicians and personnel members;
   c. How a technician may submit a complaint related to services provided;
   d. Donor records, including electronic records;
   e. A quality management program, including incident reports;
   f. Ethical practices;
   g. An infectious control program;
   h. Security, including evacuation procedures in the event of fire or disaster;
   i. NTAD and NAM inventory controls; and
   j. Contracted services;
4. SOPs for all services and activities are established, documented, and implemented for:
   a. The proper use and maintenance of a donor consent form according to A.R.S. § 36-851.03(A)(3)(a);
   b. Protocols and materials used to screen end-users prior to release and transfer of NAM according to A.R.S. § 36-851.03(A)(3)(c);
   c. Donor screening and testing plan, including:
      i. Acceptability assessment,
      ii. Donor risk assessment,
      iii. Medical records review,
      iv. Donor eligibility, and
      v. Infectious disease testing;
   d. Acquisition of NTAD;
      i. Donor verification;
      ii. Donor identity;
      iii. Acquisition records;
      iv. Packaging, including packaging insert form that discloses disease status of tissue to the end-user;
      v. Labeling;
      vi. Transport; and
      vii. Storage;
   e. Preparation methods, including:
      i. Receipt of NAM;
      ii. Prevent airborne transmission, and
      iii. Quarantine and storage, if applicable;

f. Release and transfer, including:
i. End-user eligibility review;
ii. Quality control review;
iii. Release of NAM;
iv. Exceptional release;
v. Failing review process; and
vi. Transfer to distribution for use, including out-of-state and international shipping;
g. Final disposition of donation according to A.R.S. § 36-851.03(A)(3)(f) and consistent with:
i. Board of Funeral Directors and Embalmers specified in 4 A.A.C. 12, Articles 3, 5, and 6;
ii. Vital Records and Public Health Statistics specified in A.R.S. Title 36, Chapter 3;
iii. Vital Records and Statistics specified in 9 A.A.C. 19;
iv. Health menaces specified in A.R.S. Title 36, Chapter 6, Article 1;
v. Disposition of Human Bodies specified in A.R.S. Title 36, Chapter 7; and
vi. Communicable Diseases and Infestations specified in 9 A.A.C. 6;

5. SOPs that all NTAD acquired by the procurement organization shall bear a label that:
a. Is written, printed, or graphic material used to identify NTAD/NAM, blood specimens, or other donor specimens; and
b. States according to A.R.S. § 36-851.03(A)(6)(b):
i. The NTAD or NAM is not for transplant or clinical use;
ii. Any condition and any limitation regarding the use of the NTAD or NAM;
iii. That universal precautions shall be used; and
iv. The contact information for the procurement organization;

6. SOPs are:
a. Maintained at the procurement organization and copies available to the Department for review upon request;
b. Reviewed at least once every three years and updated as needed; and
c. Available to technicians and personnel members; and

7. A loss or theft of NTAD or NAM is documented and reported to the appropriate law enforcement agency within 24 hours of discovery.

F. An administrator of a non-accredited procurement organization shall immediately report suspected misuse of NTAD or NAM.

G. An administrator of a non-accredited procurement organization shall ensure that a report specified in subsection (F) is documented and maintained in the donor's record as specified in R9-9-205(E).

H. A licensee of a non-accredited procurement organization shall ensure that the following information or documents are conspicuously posted on the premises:
1. The procurement organization's current license,
2. The name of the administrator and medical director,
3. The hours of operation, and
4. The evacuation plan listed in R9-9-302.

R9-9-202. Quality Management

A licensee of a non-accredited procurement organization shall ensure that:
1. A plan is established, documented, and implemented for an ongoing quality management program that, at a minimum, includes:
a. A method to identify, document, and evaluate incidents;
b. A method to collect data to evaluate procurement organization services provided;
c. A method to evaluate the data collected to identify a concern about the delivery of procurement organization services;
d. A method to make changes or take action as a result of the identification of a concern about the delivery of procurement organization services; and
e. The frequency of submitting a documented report required in subsection (2) to the licensee.
2. A documented report is submitted to the licensee that includes:
a. An identification of each concern about the delivery of procurement organization services; and
b. Any changes made or actions taken as a result of the identification of a concern about the delivery of procurement organization services.
3. The report required in subsection (2) and the supporting documentation for the report is maintained for 12 months by the procurement organization after the date the report is submitted to the licensee.

R9-9-203. Contracted Services

A licensee of a non-accredited procurement organization shall ensure that:
1. Contracted services are documented by agreement specified in SOPs.
2. If a procurement organization contracts with a laboratory for infectious disease testing of NAM, the contracted laboratory is registered with the Food and Drug Administration as a tissue establishment, specified in 21 C.F.R. § 1271.3, for testing and is either:
a. Certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. § 263a) and 42 C.F.R. Part 493; or
b. Meets equivalent requirements as determined by the Centers for Medicare and Medicaid Services.
3. A list of contracted service providers is maintained and includes a description of the specific services provided.

R9-9-204. Medical Director, Administrator, Technicians, and Personnel Members

A. A licensee of a non-accredited procurement organization shall ensure that the medical director:
1. Establishes, reviews, and approves all SOPs of a medical nature, including:

a. Donor eligibility related to:
i. Screenings,
ii. Testing plans,
iii. Acceptability assessment;
b. Sampling plan and methods verifying NTAD release;
c. Exceptional release criteria and processes of NAM; and
d. Pre-established release criteria;
2. Reviews all SOPs of a medical nature at least every three years;
3. Approves a designee having training and education for performing tasks and functions assigned by the medical director;
4. Has oversight and performs review of designee activities according to procedures established by the licensee;
5. Makes a determination regarding the eligibility criteria of each donor based on a comparison with predetermined donor criteria;
6. Prior to release for use or distribution, signs the donor eligibility statement and NAM disposition or release statement; and
7. Establish a criteria that ensures all appropriate parties are notified of confirmed positive infectious disease test results.

B. A licensee of a non-accredited procurement organization shall ensure that the administrator:
1. Has at least three years of experience in tissue banking or other related fields;
2. Shall define NTAD or NAM activities that a technician may provide;
3. Shall define the methods used to provide clinical oversight and training including when clinical oversight and training is provided to an individual or a group; and
4. Shall ensure a technician's personnel record includes:
a. Documentation of all completed training and education; and
b. A written job description, including all primary duties.

C. A licensee of a non-accredited procurement organization shall ensure that a technician:
1. Has the educational background, experience, and training sufficient to assure assigned tasks will be performed in accordance with the established SOPs;
2. Provides a copy of a transcript or diploma in health science or other field of science for which the technician received a degree or certificate, if applicable;
3. Demonstrates competency to perform assigned tasks; and
4. Has duties required by the technician described in a written job description.

D. A licensee of a non-accredited procurement organization shall ensure that:
1. The qualifications, skill, and knowledge required for each type of technician and personnel member is based on the activities and services a personnel member may provide as established in the personnel job description; and
2. A personnel member's qualifications, skills, and knowledge are verified and documented:
a. Before the personnel member provides procurement organization services and
b. According to SOPs.

E. A licensee of a non-accredited procurement organization shall ensure that a personnel member does not have direct interaction with NTAD and NAM unless specifically authorized by the licensee or administrator.

F. A licensee of a non-accredited procurement organization shall ensure a personnel record is established for the administrator, technicians, and personnel members that includes:
1. The individual's name, date of birth, home address, and contact telephone number;
2. The individual's starting date of employment or volunteer service and, if applicable, the ending date; and
3. Documentation applicable to an individual's duties, as required by SOPs, including the individual's:
a. Education and experience;
b. In service education and continuing education, if applicable; and
c. Evidence of Hepatitis B vaccination or refusal of Hepatitis B vaccine for individuals whose job-related responsibilities involve the potential exposure to blood-borne pathogens, if applicable.

G. A licensee of a non-accredited procurement organization shall ensure that a personnel record is:
1. Maintained throughout an individual's period of employment or volunteer service in or for the procurement organization;
2. Maintained for at least three years after the last date that an individual's employment or volunteer service in or for the procurement organization; and
3. Provided to the Department when requested.

R9-9-205. Donor Records

A. A non-accredited procurement organization shall maintain a legible, reproducible record for each donor from whom it obtains NAM for at least 10 years beyond the date of final disposition according to A.R.S. § 36-851.03(A)(7).

B. To ensure traceability of NTAD and NAM, a non-accredited procurement organization shall:
1. Document each procedure performed on a NTAD and NAM related to processing and storing NAM;
2. For each document created in subsection (1), include:
a. The date and time for each procedure completed; and
b. The name of the technician who performed the procedure; and
3. Submit information required to register the death of a NTAD within seven calendar days after receiving the NTAD according to A.R.S. § 36-325.

C. A non-accredited procurement organization shall ensure a donor record is:
1. Confidential and kept in a location with controlled access,
2. Stored in a manner to prevent unauthorized access, and
3. Maintained in a manner to preserve the donor record's completeness and accuracy.

D. A non-accredited procurement organization shall ensure a donor record shall include the following donor information:
1. The donor's name;

2. The donor's unique identifying number specified in A.R.S. § 36-851.03(A)(6);
3. The donor's date of birth and date of death; and
4. The name and contact information of the person responsible for a donor's anatomical gift; if applicable.

E. A non-accredited procurement organization shall include the following donor records, as applicable:
1. Donor consent form or documentation of authorization for an anatomical gift includes:
   a. The intended use of the NAM;
   b. How the NAM may be used;
   c. A statement that the NAM will be treated with dignity at all times; and
   d. A statement that the NAM may require international export to an end-user;
2. Document of authorization – a legal record of the gift, to take place postmortem, permitting and defining the scope of the postmortem acquisition and use of NAM for education and research, signed or otherwise recorded by the authorizing person, pursuant to law;
3. Documentation of gift – the donor's legal record of the gift of NAM permitting and defining the scope of the postmortem acquisition and use of NAM for education and research. It must be signed or otherwise recorded by the donor or individual authorized under law to make a gift during the donor's lifetime;
4. Donor's death record specified in A.A.C. R9-19-303;
5. Human remains release form specified in A.A.C. R9-19-301;
6. Information for a death record specified in A.A.C. R9-19-302 for transporting human remains into the state;
7. Disposition-transit permit specified in A.A.C. R9-19-308;
8. Medical examiner's release of information specified in A.R.S. § 36-861;
9. All documents and permits that establish the chain of custody and identifies the individuals and organizations that had physical custody of the NAM;
10. Medical records, including:
    a. Donor's physical assessment;
    b. Risk assessment questionnaire;
    c. Pathology and laboratory testing and reports;
    d. Physician summaries;
    e. Transfusion or infusion information; and
    f. Plasma dilution calculations;
11. Information from the donor referral source;
12. Donor eligibility;
13. Donor acceptability assessment;
14. Physical assessment questionnaire;
15. Documentation related to distribution;
16. Serological results, when applicable;
17. Cremation authorization document;
18. Documentation related to NAM recovery, storage, and distribution activities;
19. Final disposition documentation, including all records demonstrating chain of custody; and
20. Documentation of the report in R9-9-201(F) and (G).

F. A donor's consent form shall be accessible to the donor's known consenter.

G. Upon demonstration of a legal right to acquire a donor's record, a non-accredited procurement organization shall provide access to:
1. An agent legally authorized or other individual designated at the time a donor gives consent;
2. An individual appointed by a court or authorized by state laws;
3. An individual of a procurement organization as identified by SOPs;
4. An individual from an approving accrediting body, if applicable; and
5. An individual from the Department or other regulatory agency authorized by state and federal laws or regulations.

H. Except for a donor record specified in subsection (A), a non-accredited procurement organization shall maintain documentation required by this Chapter for at least three years after the date of the documentation and provide copies of the documentation to the Department for review upon request.

ARTICLE 3. PHYSICAL PLANT; TRANSPORTATION FOR A NON-ACCREDITED PROCUREMENT ORGANIZATION

R9-9-301. General Plant Standards; Environmental Services

A. A licensee of a non-accredited procurement organization shall ensure that a procurement organization facility:
1. Is in a building that:
   a. Has a commercial occupancy according to the local zoning jurisdiction;
   b. Is free of any plumbing, electrical, ventilation, mechanical, or structural hazard that may jeopardize the security and quality of the NTAD, NAM, and the health or safety of the public;
   c. Has equipment and supplies to maintain NTAD and NAM in a safe and temperature-controlled state; and
   d. Provides a separate and designated area for tissue recovery.
2. Has premises that are:
   a. Sufficient to provide for a procurement organization's services and activities;
   b. Cleaned and disinfected according to the procurement organization's SOPs to prevent, minimize, and control illness and infection and mitigate potential cross-contamination between NTAD and NAM;
   c. Clean and free from accumulations of dirt, garbage, and rubbish; and
   d. Free from a condition or situation that may cause an individual to suffer physical injury;
3. Provides a restroom for clients:

a. Free from contamination and cross-contamination of NAM; and
b. Does not contain any items, materials, or devices associated with the preparation activities or technicians and personnel members;
4. Implements and documents a pest control program that:
a. Requires a pest control service that uses certified applicators as specified in 3 A.A.C. 8, Article 2; and
b. Retains annual pest control service records for at least 12 months from date of service; and
5. Does not maintain a public health nuisance or engage in any act, condition, or thing, specified in A.R.S. § 36-601, or any practice contrary to the health laws of this state.

B. A licensee of a non-accredited procurement organization shall ensure that a procurement organization:
1. Has preparation rooms that:
a. Are maintained in a clean and sanitary condition at all times;
b. Are only used for examining and preparing NTAD;
c. Contain equipment, instruments, and supplies necessary for examining and preparing NTAD and are disinfected or sterilized, as applicable, after each use to protect the health and safety of technicians and personnel members;
d. Have sanitary flooring, drainage, and ventilation;
e. Have proper and convenient receptacles for refuse, bandages, and all other waste materials; and
f. Are thoroughly cleansed and disinfected with a 1% solution of chlorinated soda, or other suitable and effective disinfectant:
i. Immediately after obvious spill of blood or other potentially infectious materials, and
ii. At the end of each shift or on a regular basis that provides equivalent safety for all work surfaces;
2. Has refrigeration equipment used to store NTAD and NAM that:
a. Is only used for NTAD and NAM;
b. Is maintained in working order and kept in a clean and sanitary condition;
c. If a walk-in cooler, maintains a temperature between 36°F and 45°F;
d. If a freezer, maintains a temperature at or below 32°F;
e. Is monitored by a temperature sensor system that:
i. Measures temperatures continuously and document when a unit is out of the required temperature range, and
ii. Alert technicians or other designated individuals when temperatures are outside of the acceptable limits; and
3. Has equipment at the procurement organization that is:
a. Sufficient to support the service;
b. Maintained in working condition;
c. Maintained in a clean and sanitary condition;
d. Used according to the manufacturer's recommendations;
e. If used during an examination or preparation of NTAD, cleaned and sanitized specified in subsection (B)(1)(f)(ii); and
f. If applicable, tested and calibrated according to the manufacturer's recommendations or, if there are no manufacturer's recommendations, as specified in SOPs.

C. A licensee of a non-accredited procurement organization shall maintain documentation of equipment tests, calibrations, and repairs for at least 12 months after the date of testing, calibration, or repair.

D. A licensee of a non-accredited procurement organization shall ensure that:
1. Biohazardous material or medical waste and other potentially hazardous materials are removed and disposed by a facility licensed by the Arizona Department of Environmental Quality pursuant to 18 A.A.C. 8 and 13; and
2. Combustible or flammable liquids are stored in a labeled containers or safety containers in a secured area and properly identified to ensure individuals health and safety.

R9-9-302. Emergency and Safety Standards

A. An administrator of a non-accredited procurement organization shall ensure:
1. SOPs for emergency transfer of NTAD and NAM to a designated back up storage facility with an acceptable coolant and monitoring system in the event of mechanical failure or loss of coolant, including:
a. Tolerance limits or temperatures and time limits;
b. Methods and actions to be taken; and
c. Specific labeling indicating that the transported NTAD and NAM shall remain untouched until returned to the licensed non-accredited procurement facility after the mechanical failure or loss of coolant has been restored;
2. There is a first aid kit available at a procurement organization;
3. There are smoke detectors installed according to building size and local zoning jurisdiction;
4. A smoke detector required in subsection (A)(3):
a. Is maintained in an operable condition; and
b. Is battery operated or, if hard-wired into the electrical system of a procurement organization, has a back-up battery;
5. A procurement organization has a portable fire extinguisher that is labeled 2A-10-BC by the Underwriters Laboratory and is readily available for use;
6. A portable fire extinguisher required in subsection (A)(5) is:
a. If a disposable fire extinguisher, replaced when the fire extinguisher's indicator reaches the red zone; or
b. Serviced at least every 12 months and has a tag attached to the fire extinguisher that includes the date of service; and
7. A written fire and evacuation plan is established and maintained.

B. An administrator of a non-accredited procurement organization shall:
1. Obtain a fire inspection conducted according to the time-frame established by the local fire department or the State Fire Marshal;
2. Make any repairs or corrections stated on the fire inspection report; and

3. Maintain documentation of a current fire inspection for at least two years.

R9-9-303. Security Standards; NTAD/NAM Inventory Controls

A. A licensee of a non-accredited procurement organization shall ensure that access to the enclosed-locked areas where NTAD and NAM is located is limited to individuals authorized by the licensee or administrator.

B. To prevent unauthorized access to NTAD and NAM inventory, an administrator of a non-accredited procurement organization shall:
1. Have personnel or security equipment to deter and prevent unauthorized entrance into limited access areas that includes:
   a. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular, private radio signals, or other mechanical or electronic devices;
   b. Exterior lighting to facilitate surveillance; and
   c. Electronic monitoring using video cameras shall provide coverage of:
      i. Entrances to and exits from limited access areas;
      ii. Entrances to and exits from the buildings; and
      iii. Entrances and exits capable of identifying any activity occurring within the limited access area.
2. Maintain video recordings from the video cameras for at least 30 calendar days.
3. Have a failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system.
4. Have battery backup for video cameras and recording equipment to support in the event of a power outage.
5. SOPs:
   a. That restricts access to the areas of the building that contain NTAD and NAM inventory and donor records;
   b. That provides for identification of authorized individuals; and
   c. For conducting electronic monitoring.

C. A licensee of a non-accredited procurement organization shall establish and implement a NTAD and NAM inventory tracking system that:
1. Contains all NTAD received and NAM released for distribution;
2. Lists release documentation verified for each NAM prior to transferring NAM to inventory;
3. Documents the date, time, and location for NAM transferred for use, including the name of the individual performing the transfer;
4. Documents the date, time, and location for NAM that is moved between locations controlled by the procurement organization, including the name of the individual overseeing the move; and
5. Ensures NAM that can no longer be used is removed from inventory and disposed according to applicable SOPs.

R9-9-304. Transportation Standards

A. If a non-accredited procurement organization owns and maintains a vehicle for transporting NAM, an administrator shall ensure the vehicle is:
1. Not used for a purpose other than transporting NTAD and NAM or conducting procurement organization business;
2. Only operated by a procurement organization technician or designated individual authorized to transport NTAD or NAM;
3. Maintained in clean and sanitary condition; and
4. Locked and secured at all times during transport of NTAD or NAM.

B. If using another vehicle or type of transport for NTAD or NAM, an administrator of a non-accredited procurement organization shall ensure that another vehicle or type of transport:
1. Is properly equipped for the transportation of NTAD or NAM;
2. Is compliant with all state laws and rules pertaining to transporting human remains; and
3. If transport is by air, complies with applicable standards established by the International Air Transport Association and Transport Security Administration.

C. An administrator of a non-accredited procurement organization shall ensure that NTAD and NAM transported into the state has information of death documentation specified in A.A.C. R9-19-302 prior to transport.

R9-9-305. Sanitation Standards and Reporting

A. A licensee of a non-accredited procurement organization shall ensure that:
1. Areas used to receive, prepare, label, package, and store NAM are:
   a. Properly ventilated, and
   b. Protected from dust, dirt, flies, and other contamination.
2. All refuse and waste products produced from receiving, preparing, packaging, distributing, and transporting NAM are removed from the premises as needed.
3. All transport vehicles, trays, other receptacles, racks, tables, shelves, knives, saws, other utensils, or machinery used to move, handle, separate, package or other processes be cleaned as specified in SOPs and this Article.

B. A technician or personnel member of a non-accredited procurement organization shall report to the administrator or medical director:
1. Any concern related to receiving, preparing, packaging, distributing, or transporting NTAD or NAM that may adversely affect the health and safety of others.
2. Any personal health condition experienced related to receiving, preparing, packaging, distributing, or transporting NTAD or NAM.

C. If an administrator or medical director of a non-accredited procurement organization determines a health condition in subsection (B)(1) has occurred, the administrator or medical director shall:
1. Follow SOPs to secure the area and eliminate exposure to others;
2. Notify appropriate health and law enforcement agencies, as applicable; and

3. Report the incident to the Department within five working days of determination that a health condition in subsection (B)(2) has occurred.

D. A licensee, administrator, or medical director of a non-accredited procurement organization shall report a health condition experienced by a technician or personnel member to the Department within five calendar days of determination that the individual has a personal health condition specified in subsection (B)(1).

ARTICLE 4. ADMINISTRATION FOR AN ACCREDITED PROCUREMENT ORGANIZATION

R9-9-401. General Responsibilities

A. A licensee of an accredited procurement organization shall provide a copy of a renewed accreditation to the Department within 30 calendar days from the date of issuance.

B. A licensee of an accredited procurement organization shall ensure that a procurement organization facility is in a building that provides a separate and designated area for tissue recovery according to A.R.S. § 36-851.02(3).

C. A licensee of an accredited procurement organization shall ensure SOPs are established, documented, and implemented that cover:
1. Labeling;
2. Packaging, including a packaging insert form that discloses disease status of tissue to end-user according to A.R.S. § 36-851.02(2)(d);
3. Transport;
4. Distribution; and
5. Final disposition.

R9-9-402. Donor Consent; NTAD and NAM Identification

In addition to the requirements in Article 1, a licensee of an accredited procurement organization shall ensure that:
1. A donor consent form includes:
   a. The intended use of the NAM,
   b. How the NAM may be used,
   c. A statement that the NAM will be treated with dignity at all times, and
   d. A statement that the NAM may require international export to an end-user.
2. A donor consent form is maintained in the donor's record and retained for at least 10 years beyond the date of final disposition.
3. An electronic identification system for donors is established and maintained for NTAD or NAM;
   a. Assigns a unique identifier using a combination of letters, numbers, and symbols for NTAD or NAM;
   b. Tracks the complete history of all NAM; and
   c. Records the date and staff member involved in each significant step of the operation from the time of NTAD acquisition through final disposition.
4. The information required to register the death of a NTAD is submitted within seven calendar days after receiving the NTAD according to A.R.S. § 36-325.

R9-9-403. Tissue End-Users

A. A licensee of an accredited procurement organization shall establish, document, and implement SOPs to properly screen an end-user that includes:
1. A written request for NAM, including:
   a. The name, address and affiliation of educator and research accepting responsibility for the acceptance, use, and disposition of the NAM;
   b. A description of the intended use;
   c. The date and the approximate duration of NAM use;
   d. A description of the venue in which the NAM will be used and the security measures for the safe and ethical utilization of the venue;
   e. An assurance that universal precautions will be used when handling NAM;
   f. The proposed final disposition of the NAM;
   g. An agreement to comply with procurement organization's policies, as applicable;
   h. An outline of proposed promotional materials to be disseminated in connection with the use of NAM; and
   i. Other supporting documentation that is relevant to the request; and
2. The criteria for approving requested NAM for use, including:
   a. The acceptability of the educator and researcher for NAM utilization;
   b. The appropriateness of the intended use;
   c. Type of venue in which the NAM will be used;
   d. Proposed final disposition of the NAM unless returned to the procurement organization; and
   e. Proposed promotional materials.

B. A licensee of an accredited procurement organization shall establish, document, and implement a procedure that allows an end-users to request an exceptional release of NAM.

GOVERNOR EXECUTIVE ORDER

RULEMAKING MORATORIUM

Executive Order 2022-01 is being reproduced in each issue of the *Arizona Administrative Register* as a notice to the public regarding state agencies' rulemaking activities.

This order has been reproduced in its entirety as submitted.

EXECUTIVE ORDER 2022-01

Moratorium on Rulemaking to Promote Job Creation and Economic Development; Internal Review of Administrative Rules

[M22-03]

WHEREAS, government regulations should be as limited as possible; and

WHEREAS, burdensome regulations inhibit job growth and economic development; and

WHEREAS, in 2015 the State of Arizona implemented a moratorium on all new regulatory rulemaking by State agencies through executive order, and renewed the moratorium in 2016, 2017, 2018, 2019, 2020 and 2021; and

WHEREAS, the State of Arizona eliminated or improved 231 burdensome regulations in 2021 and for a total of 3,047 needless regulations eliminated or improved since 2015; and

WHEREAS, estimates show these eliminations saved job creators nearly $11.6 million in operating costs in 2021 for a total of over $169.1 million in savings since 2015; and

WHEREAS, in 2021, for every one new necessary rule added to the Administrative Code, 25 have been repealed or improved; and

WHEREAS, COVID-19 has been hard on small businesses and the economy, and administrative barriers should be removed for their sake; and

WHEREAS, all government agencies of the State of Arizona should continue to promote customer service oriented principles for the people that it serves; and

WHEREAS, each State agency shall continue to conduct a critical and comprehensive review of its administrative rules and take action to reduce the regulatory burden, administrative delay and legal uncertainty associated with government regulation while protecting the health, peace and safety of residents; and

WHEREAS, each State agency should continue to evaluate its administrative rules using any available and reliable data and performance metrics; and

WHEREAS, Article 5, Section 4 of the Arizona Constitution and Title 41, Chapter 1, Article 1 of the Arizona Revised Statutes vests the executive power of the State of Arizona in the Governor.

NOW, THEREFORE, I, Douglas A. Ducey, by virtue of the authority vested in me by the Constitution and laws of the State of Arizona hereby declare the following:

1. A State agency subject to this Order shall not conduct any rulemaking, including regular, expedited, emergency and exempt, whether informal or formal, without the prior written approval of the Office of the Governor. In seeking approval, a State agency shall address one or more of the following as justifications for the rulemaking:
   a. To fulfill an objective related to job creation, economic development or economic expansion in this State.
   b. To reduce or ameliorate a regulatory burden on the public, while achieving the same regulatory objective.
   c. To prevent a significant threat to public health, peace or safety.
   d. To avoid violating a court order or federal law that would result in sanctions by a federal court for failure to conduct the rulemaking action.
   e. To comply with a federal statutory or regulatory requirement if such compliance is related to a condition for the receipt of federal funds or participation in any federal program.
   f. To comply with a new state statutory requirement.
   g. To fulfill an obligation related to fees or any other action necessary to implement the State budget that is certified by the Governor's Office of Strategic Planning and Budgeting.
   h. To promulgate a rule or other item that is exempt from Title 41, Chapter 6, Arizona Revised Statutes, pursuant to section 41-1005, Arizona Revised Statutes.
   i. To address matters pertaining to the control, mitigation, or eradication of waste, fraud, or abuse within an agency or wasteful, fraudulent or abusive activities perpetrated against an agency.
   j. To eliminate rules which are antiquated, redundant or otherwise no longer necessary for the operation of state government.
2. After the public comment period and the close of the rulemaking record, a State agency subject to this Order shall not submit the proposed rules to the Governor's Regulatory Review Council without a written final approval from the Office of the Governor. Before considering rules submitted by a State agency, the Governor's Regulatory Review Council must obtain from the State agency the initial approval, referenced in Section 1, and the final approval from the Office of the Governor.
3. A State agency that submits a rulemaking request pursuant to this Order shall recommend for consideration by the Governor's Office at least *three* existing rules to eliminate for every *one* additional rule requested by the agency.

4. A State agency subject to this Order shall not publicize any directives, policy statements, documents or forms on its website unless such are explicitly authorized by the Arizona Revised Statutes or Arizona Administrative Code. Any material that is not specifically authorized must be removed immediately.
5. A State agency that issues occupational or professional licenses shall prominently post on the agency's website landing page all current state policies that ease licensing burdens and the exact steps applicants must complete to receive their license using these policies. State agencies should provide information that applies to all applicants, but have a designated area on the landing page that includes licensing information specifically for military spouses, active duty service members and veterans and all policies that make it easier for these applicant groups to receive their license. Examples of reduced licensing burdens include "universal recognition" of out-of-state licenses, availability of temporary licenses, fee waivers, exam exemptions and/or allowing an applicant to substitute military education or experience for licensing requirements. A landing page feature may link to an internal agency web page with more information, if necessary. All information must be easy to locate and written in clear and concise language.
6. A State agency that issues occupational or professional licenses must track veteran and military spouse status of applicants immediately and report that information to the Governor's Office on an annual basis, starting July 1, 2022.
7. All State agencies that are required to issue occupational or professional licenses by "universal recognition" (established by A.R.S. § 32-4302) must track all applications received for this license type immediately and report that information to the Governor's Office on an annual basis, starting July 1, 2021. Before any agency denies a professional or occupational license applied for under A.R.S. § 32-4302, the agency shall submit the application and justification for denial to the Office of the Governor for review before any official action is taken by the agency. The Governor's Office should be notified of any required timeframes, whether in statute or rule, for approval or denial of the license by the agency.
8. For the purposes of this Order, the term "State agencies" includes, without limitation, all executive departments, agencies, offices, and all state boards and commissions, except for: (a) any State agency that is headed by a single elected State official; (b) the Corporation Commission; and (c) any board or commission established by ballot measure during or after the November 1998 general election. Those state agencies, boards and commissions excluded from this Order are strongly encouraged to voluntarily comply with this Order in the context of their own rulemaking processes.
9. This Order does not confer any legal rights upon any persons and shall not be used as a basis for legal challenges to rules, approvals, permits, licenses or other actions or to any inaction of a State agency. For the purposes of this Order, "person," "rule" and "rulemaking" have the same meanings prescribed in section 41-1001, Arizona Revised Statutes.
10. This Executive Order shall expire when the provisions of this executive order are adopted in statute and become law.

IN WITNESS THEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Arizona.

Douglas A. Ducey
GOVERNOR

DONE at the Capitol in Phoenix on this nineteenth day of January in the year Two Thousand and Twenty Two and of the Independence of the United States of America the Two Hundred and Forty-Sixth.

ATTEST:

Katie Hobbs
SECRETARY OF STATE

REGISTER INDEXES

The *Register* is published by volume in a calendar year (See "General Information" in the front of each issue for more information).

Abbreviations for rulemaking activity in this Index include:

PROPOSED RULEMAKING
PN = Proposed new Section
PM = Proposed amended Section
PR = Proposed repealed Section
P# = Proposed renumbered Section

SUPPLEMENTAL PROPOSED RULEMAKING
SPN = Supplemental proposed new Section
SPM = Supplemental proposed amended Section
SPR = Supplemental proposed repealed Section
SP# = Supplemental proposed renumbered Section

FINAL RULEMAKING
FN = Final new Section
FM = Final amended Section
FR = Final repealed Section
F# = Final renumbered Section

SUMMARY RULEMAKING
PROPOSED SUMMARY
PSMN = Proposed Summary new Section
PSMM = Proposed Summary amended Section
PSMR = Proposed Summary repealed Section
PSM# = Proposed Summary renumbered Section
FINAL SUMMARY
FSMN = Final Summary new Section
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FSMR = Final Summary repealed Section
FSM# = Final Summary renumbered Section

EXPEDITED RULEMAKING
PROPOSED EXPEDITED
PEN = Proposed Expedited new Section
PEM = Proposed Expedited amended Section
PER = Proposed Expedited repealed Section
PE# = Proposed Expedited renumbered Section
SUPPLEMENTAL EXPEDITED
SPEN = Supplemental Proposed Expedited new Section
SPEM = Supplemental Proposed Expedited amended Section
SPER = Supplemental Proposed Expedited repealed Section
SPE# = Supplemental Proposed Expedited renumbered Section
FINAL EXPEDITED
FEN = Final Expedited new Section
FEM = Final Expedited amended Section
FER = Final Expedited repealed Section
FE# = Final Expedited renumbered Section

EXEMPT RULEMAKING
EXEMPT
XN = Exempt new Section
XM = Exempt amended Section
XR = Exempt repealed Section
X# = Exempt renumbered Section
EXEMPT PROPOSED
PXN = Proposed Exempt new Section
PXM = Proposed Exempt amended Section
PXR = Proposed Exempt repealed Section
PX# = Proposed Exempt renumbered Section
EXEMPT SUPPLEMENTAL PROPOSED
SPXN = Supplemental Proposed Exempt new Section
SPXR = Supplemental Proposed Exempt repealed Section
SPXM = Supplemental Proposed Exempt amended Section
SPX# = Supplemental Proposed Exempt renumbered Section
FINAL EXEMPT RULEMAKING
FXN = Final Exempt new Section
FXM = Final Exempt amended Section
FXR = Final Exempt repealed Section
FX# = Final Exempt renumbered Section

EMERGENCY RULEMAKING
EN = Emergency new Section
EM = Emergency amended Section
ER = Emergency repealed Section
E# = Emergency renumbered Section
EEXP = Emergency expired

RECODIFICATION OF RULES
RC = Recodified

REJECTION OF RULES
RJ = Rejected by the Attorney General

TERMINATION OF RULES
TN = Terminated proposed new Sections
TM = Terminated proposed amended Section
TR = Terminated proposed repealed Section
T# = Terminated proposed renumbered Section

RULE EXPIRATIONS
EXP = Rules have expired
See also "emergency expired" under emergency rulemaking

CORRECTIONS
C = Corrections to Published Rules

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RULEMAKING ACTIVITY INDEX

Rulemakings are listed in the Index by Chapter, Section number, rulemaking activity abbreviation and volume page number. Use the page guide above to determine the *Register* issue number to review the rule. Headings for the Subchapters, Articles, Parts, and Sections are not indexed.

THIS INDEX INCLUDES RULEMAKING ACTIVITY THROUGH ISSUE 25 OF VOLUME 28.

Secretary of State, Office of the

Transportation, Department of - Oversize and Overweight Special Permits

Transportation, Department of - Title, Registration, and Driver Licenses

Water Resources, Department of

OTHER NOTICES AND PUBLIC RECORDS INDEX

Other legal notices required to be published under the Administrative Procedure Act, such as Rulemaking Docket Openings, are included in this Index by volume page number. Notices of Agency Ombudsman, Substantive Policy Statements, Proposed Delegation Agreements, and other applicable public records as required by law are also listed in this Index by volume page number.

THIS INDEX INCLUDES OTHER NOTICE ACTIVITY THROUGH ISSUE 25 OF VOLUME 28.

Agency Guidance Document, Notices of

Agency Ombudsman, Notices of

Docket Opening, Notices of Rulemaking

Final Delegation Agreement, Notices of

Governor's Office

Governor's Regulatory Review Council

Oral Proceeding, Notices of

Proposed Delegation Agreement, Notices of

Public Information, Notices of

Substantive Policy Statement, Notices of

RULES EFFECTIVE DATES CALENDAR

A.R.S. § 41-1032(A), as amended by Laws 2002, Ch. 334, § 8 (effective August 22, 2002), states that a rule generally becomes effective 60 days after the day it is filed with the Secretary of State's Office. The following table lists filing dates and effective dates for rules that follow this provision. Please also check the rulemaking Preamble for effective dates.

January		**February**		**March**		**April**		**May**		**June**	
Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date
1/1	3/2	2/1	4/2	3/1	4/30	4/1	5/31	5/1	6/30	6/1	7/31
1/2	3/3	2/2	4/3	3/2	5/1	4/2	6/1	5/2	7/1	6/2	8/1
1/3	3/4	2/3	4/4	3/3	5/2	4/3	6/2	5/3	7/2	6/3	8/2
1/4	3/5	2/4	4/5	3/4	5/3	4/4	6/3	5/4	7/3	6/4	8/3
1/5	3/6	2/5	4/6	3/5	5/4	4/5	6/4	5/5	7/4	6/5	8/4
1/6	3/7	2/6	4/7	3/6	5/5	4/6	6/5	5/6	7/5	6/6	8/5
1/7	3/8	2/7	4/8	3/7	5/6	4/7	6/6	5/7	7/6	6/7	8/6
1/8	3/9	2/8	4/9	3/8	5/7	4/8	6/7	5/8	7/7	6/8	8/7
1/9	3/10	2/9	4/10	3/9	5/8	4/9	6/8	5/9	7/8	6/9	8/8
1/10	3/11	2/10	4/11	3/10	5/9	4/10	6/9	5/10	7/9	6/10	8/9
1/11	3/12	2/11	4/12	3/11	5/10	4/11	6/10	5/11	7/10	6/11	8/10
1/12	3/13	2/12	4/13	3/12	5/11	4/12	6/11	5/12	7/11	6/12	8/11
1/13	3/14	2/13	4/14	3/13	5/12	4/13	6/12	5/13	7/12	6/13	8/12
1/14	3/15	2/14	4/15	3/14	5/13	4/14	6/13	5/14	7/13	6/14	8/13
1/15	3/16	2/15	4/16	3/15	5/14	4/15	6/14	5/15	7/14	6/15	8/14
1/16	3/17	2/16	4/17	3/16	5/15	4/16	6/15	5/16	7/15	6/16	8/15
1/17	3/18	2/17	4/18	3/17	5/16	4/17	6/16	5/17	7/16	6/17	8/16
1/18	3/19	2/18	4/19	3/18	5/17	4/18	6/17	5/18	7/17	6/18	8/17
1/19	3/20	2/19	4/20	3/19	5/18	4/19	6/18	5/19	7/18	6/19	8/18
1/20	3/21	2/20	4/21	3/20	5/19	4/20	6/19	5/20	7/19	6/20	8/19
1/21	3/22	2/21	4/22	3/21	5/20	4/21	6/20	5/21	7/20	6/21	8/20
1/22	3/23	2/22	4/23	3/22	5/21	4/22	6/21	5/22	7/21	6/22	8/21
1/23	3/24	2/23	4/24	3/23	5/22	4/23	6/22	5/23	7/22	6/23	8/22
1/24	3/25	2/24	4/25	3/24	5/23	4/24	6/23	5/24	7/23	6/24	8/23
1/25	3/26	2/25	4/26	3/25	5/24	4/25	6/24	5/25	7/24	6/25	8/24
1/26	3/27	2/26	4/27	3/26	5/25	4/26	6/25	5/26	7/25	6/26	8/25
1/27	3/28	2/27	4/28	3/27	5/26	4/27	6/26	5/27	7/26	6/27	8/26
1/28	3/29	2/28	4/29	3/28	5/27	4/28	6/27	5/28	7/27	6/28	8/27
1/29	3/30			3/29	5/28	4/29	6/28	5/29	7/28	6/29	8/28
1/30	3/31			3/30	5/29	4/30	6/29	5/30	7/29	6/30	8/29
1/31	4/1			3/31	5/30			5/31	7/30		

July		**August**		**September**		**October**		**November**		**December**	
Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date	Date Filed	Effective Date
7/1	8/30	8/1	9/30	9/1	10/31	10/1	11/30	11/1	12/31	12/1	1/30
7/2	8/31	8/2	10/1	9/2	11/1	10/2	12/1	11/2	1/1	12/2	1/31
7/3	9/1	8/3	10/2	9/3	11/2	10/3	12/2	11/3	1/2	12/3	2/1
7/4	9/2	8/4	10/3	9/4	11/3	10/4	12/3	11/4	1/3	12/4	2/2
7/5	9/3	8/5	10/4	9/5	11/4	10/5	12/4	11/5	1/4	12/5	2/3
7/6	9/4	8/6	10/5	9/6	11/5	10/6	12/5	11/6	1/5	12/6	2/4
7/7	9/5	8/7	10/6	9/7	11/6	10/7	12/6	11/7	1/6	12/7	2/5
7/8	9/6	8/8	10/7	9/8	11/7	10/8	12/7	11/8	1/7	12/8	2/6
7/9	9/7	8/9	10/8	9/9	11/8	10/9	12/8	11/9	1/8	12/9	2/7
7/10	9/8	8/10	10/9	9/10	11/9	10/10	12/9	11/10	1/9	12/10	2/8
7/11	9/9	8/11	10/10	9/11	11/10	10/11	12/10	11/11	1/10	12/11	2/9
7/12	9/10	8/12	10/11	9/12	11/11	10/12	12/11	11/12	1/11	12/12	2/10
7/13	9/11	8/13	10/12	9/13	11/12	10/13	12/12	11/13	1/12	12/13	2/11
7/14	9/12	8/14	10/13	9/14	11/13	10/14	12/13	11/14	1/13	12/14	2/12
7/15	9/13	8/15	10/14	9/15	11/14	10/15	12/14	11/15	1/14	12/15	2/13
7/16	9/14	8/16	10/15	9/16	11/15	10/16	12/15	11/16	1/15	12/16	2/14
7/17	9/15	8/17	10/16	9/17	11/16	10/17	12/16	11/17	1/16	12/17	2/15
7/18	9/16	8/18	10/17	9/18	11/17	10/18	12/17	11/18	1/17	12/18	2/16
7/19	9/17	8/19	10/18	9/19	11/18	10/19	12/18	11/19	1/18	12/19	2/17
7/20	9/18	8/20	10/19	9/20	11/19	10/20	12/19	11/20	1/19	12/20	2/18
7/21	9/19	8/21	10/20	9/21	11/20	10/21	12/20	11/21	1/20	12/21	2/19
7/22	9/20	8/22	10/21	9/22	11/21	10/22	12/21	11/22	1/21	12/22	2/20
7/23	9/21	8/23	10/22	9/23	11/22	10/23	12/22	11/23	1/22	12/23	2/21
7/24	9/22	8/24	10/23	9/24	11/23	10/24	12/23	11/24	1/23	12/24	2/22
7/25	9/23	8/25	10/24	9/25	11/24	10/25	12/24	11/25	1/24	12/25	2/23
7/26	9/24	8/26	10/25	9/26	11/25	10/26	12/25	11/26	1/25	12/26	2/24
7/27	9/25	8/27	10/26	9/27	11/26	10/27	12/26	11/27	1/26	12/27	2/25
7/28	9/26	8/28	10/27	9/28	11/27	10/28	12/27	11/28	1/27	12/28	2/26
7/29	9/27	8/29	10/28	9/29	11/28	10/29	12/28	11/29	1/28	12/29	2/27
7/30	9/28	8/30	10/29	9/30	11/29	10/30	12/29	11/30	1/29	12/30	2/28
7/31	9/29	8/31	10/30			10/31	12/30			12/31	3/1

REGISTER PUBLISHING DEADLINES

The Secretary of State's Office publishes the Register weekly. There is a three-week turnaround period between a deadline date and the publication date of the Register. The weekly deadline dates and issue dates are shown below. Council meetings and Register deadlines do not correlate. Also listed are the earliest dates on which an oral proceeding can be held on proposed rulemakings or proposed delegation agreements following publication of the notice in the Register.

Deadline Date Friday, 5:00 p.m. *(*earlier date due to holiday)*	***Register* Publication Date**	**Oral Proceeding may be scheduled on or after**
December 30, 2021	January 21, 2022	February 22, 2022
January 7, 2022	January 28, 2022	February 28, 2022
January 14, 2022	February 4, 2022	March 7, 2022
January 21, 2022	February 11, 2022	March 14, 2022
January 28, 2022	February 18, 2022	March 21, 2022
February 4, 2022	February 25, 2022	March 28, 2022
February 11, 2022	March 4, 2022	April 4, 2022
February 18, 2022	March 11, 2022	April 11, 2022
February 25, 2022	March 18, 2022	April 18, 2022
March 4, 2022	March 25, 2022	April 25, 2022
March 11, 2022	April 1, 2022	May 2, 2022
March 18, 2022	April 8, 2022	May 9, 2022
March 25, 2022	April 15, 2022	May 16, 2022
April 1, 2022	April 22, 2022	May 23, 2022
April 8, 2022	April 29, 2022	May 31, 2022
April 15, 2022	May 6, 2022	June 6, 2022
April 22, 2022	May 13, 2022	June 13, 2022
April 29, 2022	May 20, 2022	June 20, 2022
May 6, 2022	May 27, 2022	June 27, 2022
May 13, 2022	June 3, 2022	July 5, 2022
May 20, 2022	June 10, 2022	July 11, 2022
May 27, 2022	June 17, 2022	July 18, 2022
June 3, 2022	June 24, 2022	July 25, 2022
June 10, 2022	July 1, 2022	August 1, 2022
June 17, 2022	July 8, 2022	August 8, 2022
June 24, 2022	July 15, 2022	August 15, 2022
July 1, 2022	July 22, 2022	August 22, 2022
July 8, 2022	July 29, 2022	August 29, 2022
July 15, 2022	August 5, 2022	September 6, 2022

GOVERNOR'S REGULATORY REVIEW COUNCIL DEADLINES

The following deadlines apply to all Five-Year Review Reports and any adopted rule submitted to the Governor's Regulatory Review Council. Council meetings and *Register* deadlines do not correlate. We publish these deadlines under A.R.S. § 41-1013(B)(15).

All rules and Five-Year Review Reports are due in the Council office by 5 p.m. of the deadline date. The Council's office is located at 100 N. 15th Ave., Suite 305, Phoenix, AZ 85007. For more information, call (602) 542-2058 or visit http://grrc.az.gov.

GOVERNOR'S REGULATORY REVIEW COUNCIL DEADLINES FOR 2022

(MEETING DATES ARE SUBJECT TO CHANGE)

DEADLINE FOR PLACEMENT ON AGENDA*	FINAL MATERIALS SUBMITTED TO COUNCIL	DATE OF COUNCIL STUDY SESSION	DATE OF COUNCIL MEETING
Tuesday January 18, 2022	*Tuesday* February 15, 2022	*Tuesday* February 22, 2022	*Tuesday* March 1, 2022
Tuesday February 15, 2022	*Tuesday* March 22, 2022	*Tuesday* March 29, 2022	*Tuesday* April 5, 2022
Tuesday March 22, 2022	*Tuesday* April 19, 2022	*Tuesday* April 26, 2022	*Tuesday* May 3, 2022
Tuesday April 19, 2022	*Tuesday* May 17, 2022	*Tuesday* May 24, 2022	***Wednesday*** June 1, 2022
Tuesday May 17, 2022	*Tuesday* June 21, 2022	*Tuesday* June 28, 2022	***Wednesday*** July 6, 2022
Tuesday June 21, 2022	*Tuesday* July 19, 2022	*Tuesday* July 26, 2022	*Tuesday* August 2, 2022
Tuesday July 19, 2022	*Tuesday* August 23, 2022	*Tuesday* August 30, 2022	***Wednesday*** September 7, 2022
Tuesday August 23, 2022	*Tuesday* September 20, 2022	*Tuesday* September 27, 2022	*Tuesday* October 4, 2022
Tuesday September 20, 2022	*Tuesday* October 18, 2022	*Tuesday* October 25, 2022	*Tuesday* November 1, 2022
Tuesday October 18, 2022	*Tuesday* November 22, 2022	*Tuesday* November 29, 2022	*Tuesday* December 6, 2022

* Materials must be submitted by **5 PM** on dates listed as a deadline for placement on a particular agenda. Placement on a particular agenda is not guaranteed.